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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/574,460	05/18/2000	Michael A. Apicella	875.009US1	6817

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EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/574,460	APICELLA ET AL.	
	Examiner	Art Unit	
	Yong D Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *22,23* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed on May 5, 2003, canceling claims 1-29 and adding new claims 30-55, has been entered.

Claims 30-55 are pending.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on May 5, 2003 and July 2, 2003 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30-32, 34-41, 43-50 and 52-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin et al. in view of Alexander et al.

McLaughlin et al. (form PTO-1449) teach a process for production of *H. influenzae*-specific lipooligosaccharides (or complex carbohydrates) using a

lipooligosaccharide-synthesis gene (lsg) from *H. influenzae* (pages 166-167). McLaughlin et al. teach that the various sugar transferases expressed from the lsg are responsible for the modification of the existing E. coli LPS (page 172). LsgG is among the 8 ORF taught by McLaughlin et al. Since the LsgG protein of McLaughlin et al. and the LsgG protein of the instant invention is identical, regulation of *rfe* by LsgG is an inherent property of LsgG. McLaughlin et al. also teach that the lipooligosaccharides of *H. influenzae* are important virulence factors for this pathogen.

The difference between the reference of McLaughlin et al. and the instant invention is that the reference of McLaughlin et al. does not teach a process of making the lipooligosaccharide using an rfe enzyme.

Alexander et al. (form PTO-1449) teach an *E. coli* rfe and that the enzyme is essential for the first step in the biosynthesis of lipooligosaccharide (page 7079). Alexander et al. also teach that rfe plays a role in O-specific polysaccharides (page 7079 and 7083).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make lipooligosaccharides with a *E. coli* K-12 expressing an *E. coli* rfe and a *H. influenzae* lsg. The motivation of using an rfe gene with an lsg gene comprising the lsg gene is that rfe is essential for the first step in the biosynthesis of oligosaccharides. The motivation of producing lipooligosaccharide in large amounts is to effectively obtain oligosaccharides, useful in developing vaccines and in identification of the *H. influenzae* bacteria itself. One of ordinary skill in the art

would have had a reasonable expectation of success since recombinant technology is performed routinely in the art.

Claims 30, 33, 39, 42, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin et al. in view of Alexander et al., further in view of Swierzko et al.

The references of McLaughlin et al. and Alexander et al. in combination teach a process of making lipooligosaccharides with a lsg gene and a rfe gene with a E. coli bearing a terminal heptose molecule, as discussed above.

The difference between the combined teaching of McLaughlin et al. and Alexander et al. and the instant invention is that the reference of the combined teachings does not teach a process of making the lipooligosaccharide using a *Salmonella minnesota* bacterium.

Swierzko et al. teach that *S. minnesota* bears a terminal heptose molecule and teaches the use of this bacterium in synthesizing lipooligosaccharides (pages 3216-3217). *S. minnesota* is an useful bacteria because of their rapid growth in the laboratory.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make lipooligosaccharides with a *S. minnesota* expressing an *E. coli* rfe and a H. influenzae lsg. The motivation of making using *S. minnesota* is out of conveniences since *S. minnesota* grow rapidly and are used in the art for lipooligosaccharides synthesis. One of ordinary skill in the art would have had a reasonable expectation of success since *S. minnesota* are easy to work and weii known in the art.

Response to Arguments

Applicant's arguments filed on May 5, 2003 have been fully considered but they are not persuasive.

Applicants argue that there is no teaching or suggestion of using an rfe gene with the lsgG gene. The examiner disagrees. McLaughlin et al. teach "it is likely that the lsg locus should contain a series of genes coding for sugar transferases" (page 172, 2nd column). Therefore, there is enough suggestion in the reference of McLaughlin et al. to use a gene comprising a gene encoding the LsgG protein.

Further, as addressed above, since the LsgG protein of McLaughlin et al. and the LsgG protein of the instant invention is identical, regulation of *rfe* by LsgG is an inherent property of LsgG.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

September 30, 2003